REMARKS/ARGUMENTS

Claims 1-22 and 24-32 are pending in the current application. Claims 16-19 and 25-32 were withdrawn from consideration by the Examiner as being drawn to nonelected inventions. Claim 23 has been canceled.

Claim 11 has been amended. Support for this amendment may be found in original Claim 12 and PCT amended Claim 11. No new matter is added.

Election/Restriction

The Examiner states that the required election of species was not made in the reply filed on July 2, 2007. However, Applicants respectfully submit that "Species A, a specific capsular saccharide antigen as stated in claims 2 and 6 as well as claims 5, 8 and 10" was elected on July 2, 2007 (page 3, first paragraph).

Information Disclosure Statement

WO96/40077, WO99/13906 and WO98/00167 were not considered since "PCT" was entered as the country code. Applicants submit herewith an IDS with these patent documents with "WO" as the country code. Applicants respectfully request consideration of these documents by the Examiner.

Claim Rejections

35 U.S.C. 103

Claims 1-12, 20 and 21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Boutriau et al. (US2003/0180316 A1) and Truong-Le, Vu (US 7,135,180 B2, hereinafter "Troung-Le, Vu"). Applicants respectfully submit that Boutriau et al. shall not preclude patentability under 35 U.S.C. 103(a) as this application and Boutriau et al. were subject to an obligation of assignment to GlaxoSmithKline Biologicals S.A. at the time this invention was made. Therefore, Boutriau et al. and the present invention are commonly owned. 35 U.S.C. 103(c)(1). M.P.E. P. 706.02(l)(2). Applicants respectfully request that this rejection be withdrawn.

Claims 1-4, 11-13 and 24 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kurikka et al. (Journal of Pediatrics, 1996) and Truong-Le,Vu. Applicants respectfully traverse this rejection.

The Supreme Court has stated that the *Graham* factors continue to define the inquiry that controls in determining if the claimed subject matter is obvious under § 103. *KSR Int'l Co. v. Teleflex Inc.,* 127 S. Ct. 1727, 1734 (2007). "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l v. Teleflex Inc.* (550 U.S. ___, 127 S. Ct. 1727, 2007, 82 USPQ2d 1385, 1396, (quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006))). Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness for at least the reason that the Examiner has failed to establish a rational underpinning to support the legal conclusion of obviousness based on the *Graham* factors.

To reject claims based on the rationale of combining prior art elements according to known methods to yield predictable results, the Examiner must articulate:

> (1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference;
>
> (2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely would have performed the same function as it did separately;
>
> (3) a finding that one of ordinary skill in the art would have recognized that the results of the combination were predictable; and
>
> (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

72 Fed. Reg. 57526, 57529 (October 10, 2007).

The Examiner has failed to establish (1) that the prior art discloses each element claimed, (2) that in combination each element would have performed the

same function as it did separately, and (3) that the results of the combination were predictable.

First, the prior art does not include each element as claimed by Applicants. It does not disclose or suggest an immunogenic composition comprising IPV, a bacterial polysaccharide or oligosaccharide and a stabilizing agent, all formulated as a dried composition, which after reconstitution, is capable of generating an immune response against polio virus, as recited in Applicants' independent Claim 1.

Kurikka et al. do not disclose a single immunogenic composition comprising IPV, a bacterial polysaccharide or oligosaccharide and a stabilizing agent, nor does it disclose such a composition formulated as a dried composition. In contrast, Kurikka et al. compare seroresponses to five different vaccination schedules for *Haemophilus influenzae* type b-tetanus toxoid conjugate. (abstract). IPV was merely administered concurrently with the PRP-T and DTP vaccines, not within the same immunogenic composition. The PRP-T and DTP vaccines were given intramuscularly in the right buttock and IPV was administered concurrently in the left buttock. (page 525, third paragraph). Additionally, Kurikka et al. did not disclose use of a dried immunogenic composition comprising IPV, as claimed by Applicants. Therefore, Kurikka et al. do not include all the limitations of independent Claim 1, an immunogenic composition comprising IPV, a bacterial polysaccharide or oligosaccharide and a stabilizing agent, all formulated as a dried composition, which after reconstitution, is capable of generating an immune response against polio virus.

Truong-Le, Vu does not make up for the deficiencies of Kurikka et al. Truong-Le, Vu only provides "methods and compositions to preserve bioactive materials in a dried foam matrix." (abstract). While Truong-Le, Vu provides a long list of examples of viruses that could be preserved, such as influenza virus, parainfluenza virus, AAV, adenovirus, respiratory syncytial virus, herpes simplex virus, cytomegalovirus, SARS virus, corona virus family members, human metapneumovirus, and Epstein-Barr virus, it does not suggest preserving IPV. (column 14, lines 27-32). Therefore, Truong-Le, Vu also fails to disclose an immunogenic composition comprising IPV, a bacterial polysaccharide or oligosaccharide and a stabilizing agent, all formulated as a dried composition, which

after reconstitution, is capable of generating an immune response against polio virus. Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness for at least the reason that Kurikka et al. in view of Truong-Le, Vu do include each of the claim limitations.

Secondly, nothwithstanding the failure of the prior art to include each element claimed, one of ordinary skill in the art would not have been motivated to combine the elements as claimed by known methods. There would have been no motivation to prepare an immunogenic composition by known methods of drying because there was no expectation of success. For example, at the time of Applicants filing there was no successful example of making a dried solid vaccine formulation of IPV that retains a high degree of antigenicity and/or immunogenicity. (page 3, lines 6-7, Applicants specification). The process of freeze-drying IPV had been associated with the loss of antigenicity so it was difficult to formulate an effective vaccine comprising a dried form of IPV (page 1, lines 16-18, Applicants' specification). Therefore, one of ordinary skill would not have been motivated to combine the elements as claimed by known methods.

Thirdly, notwithstanding (1) the failure of the prior art to include each element claimed and (2) that one of ordinary skill in the art would not have been motivated to combine the elements as claimed by known methods, the results of the combination were not predictable. Applicants have shown that the presence of both IPV and a bacterial polysaccharide or oligosaccharide work together in an unexpected and fruitful manner - a greater degree of IPV antigenicity is retained following drying and reconstitution when a bacterial polysaccharide is used than when standard stabilizing agents are used. See for instance, Example 6, where the addition of a bacterial polysaccharide results in a large improvement in the degree of antigenicity remaining for IPV type 1 and 2 after freeze drying, with ELISA readings increasing from 26% and 25% to 52% and 68%, respectively, with the addition of Hib polysaccharides. That the claimed elements work together in an unexpected and fruitful manner support that the claimed immunogenic composition is not obvious to those skilled in the art. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740, 82 USPQ2d 1385, 1395 (2007).

Applicants respectfully submit that the Examiner has failed to establish a prima facie case of obviousness for Claim 1 over Kurikka et al. and Truong-Le, Vu. The prior art does not include each element claimed, one of ordinary skill in the art would not have combined the elements as claimed by known methods, and the results of the combination were not predictable.

Applicants respectfully submit that Claim 1 is patentable over Kurikka et al. and Truong-Le, Vu. Claims 2-4, 11-13, 22 and 24 depend directly or indirectly from patentable independent Claim 1. For at least this reason and without acquiescing in the Office Action's separate rejection of these dependent claims, Applicants respectfully submit that Claims 2-4, 11-13, 22 and 24 are also patentable. Accordingly, Applicants respectfully request that these rejections be withdrawn.

35 U.S.C. 112

Claims 14 and 15 were rejected under 35 USC 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection and submit that Claims 14 and 15 set forth the claimed subject matter with a reasonable degree of clarity and particularity in light of their disclosure. Definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. MPEP 2173.02.

Applicants have defined both a "dried solid composition" and a "highly viscous liquid" in their specification. A dried solid composition is described on page 6, lines 24-30:

> A dried solid is a formulation which has had solvent removed by a process of lyophilisation, sublimation, evaporation or dessication so that less than or equal to 15%, 12%, 10%, 7%, 5% , 4%, preferably 3%, 2% or most preferably 1% solvent remains.

A highly viscous liquid is defined on page 7, lines 1-2, as "a material with a solvent content less than or equal to 15, 12, 10, preferably 8, 5, 4, 3, 2, or 1%."

In view of Applicants disclosure it is clear how a highly viscous composition may have the same properties as a dried solid composition. Applicants respectfully

submit that Claims 14 and 15 set forth the claimed subject matter with a reasonable degree of clarity and particularity and request that this rejection be withdrawn.

Claim 23 has been rejected under 35 USC 112, second paragraph, as being indefinite. Claim 23 has been canceled rendering this rejection moot. Applicants respectfully request that this rejection be withdrawn.

OBJECTIONS

Claim 12 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 11. An inadvertent typographical error occurred in Claim 11 during preparation of the preliminary amendment. Claim 11 has been amended to the text of Claim 11 as presented in the amended PCT claims, without its multiple dependency. Applicants respectfully submit that Claim 12 is no longer duplicative of Claim 11 and respectfully request that this objection be withdrawn.

CONCLUSION

Should any outstanding issues remain, the Examiner is encouraged to contact Applicants' undersigned representative.

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